



DECLARATION OF DANIEL J. COOK UNDER 37 C.F.R. §1.132

In re: RETAINER FOR LARYNGEAL MASK

Serial No.: 10/072,247

Our File No.: COOK 8715C1

File: 10/23/2001

I, Daniel J. Cook, do hereby declare that:

1. I am a Board Certified MD Anesthesiologist with over 16 years of clinical experience in the field of anesthesiology. (See Exhibit 1 - Resume of Dr. Daniel J. Cook)
2. I am the inventor of the invention claimed in U.S. Patent Application Serial Number 10/072,247.
3. I am an expert in the field of airways, airway devices and airway management.
4. I have been involved in the creation and design of laryngeal masks and other airway devices for approximately 6 years.
5. It is understood and well known to those skilled in the art of airways, airway devices and airway management that endotracheal tubes are manufactured in sizes ranging from an internal diameter (ID) of 2.0 millimeters (mm) to 11.0 mm. It is not possible to purchase an endotracheal tube having an ID outside of this range. (See Exhibit 2 - On-line catalogues from various major medical equipment supply companies selling endotracheal tubes)
6. Anesthesiologists are integral parts of surgical teams, and are, therefore, present for the placement of endocardiac devices such as defibrillators and pacemakers,

which employ endocardial leads. Therefore, anyone skilled in the art of anesthesiology would know the physical size of endocardial leads.

7. I have a good working knowledge of the physical sizes of leads.

8. Endocardial leads have outside diameters (OD) of approximately 2.5-2.7 mm. It is well known and understood by those skilled in the medical arts that endocardial leads have an IO of less than approximately 1 mm. (See Exhibit 3 - On-line catalogue of major medical supply company selling endocardial leads)

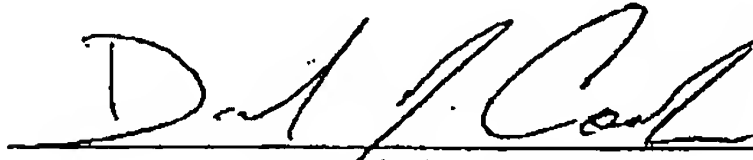
9. Therefore, it is well known and understood by those skilled in the art that the endocardial lead extraction devices, including those of McCorkle, Jr., U.S. Patent Number 4,582,056 ('056 patent), must have a ODs that are in the range of approximately 1 mm to approximately 1.5 mm in order to sufficiently engage a endocardial lead, thereby facilitating extraction.

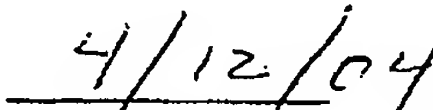
10. The invention claimed in U.S. Patent Application Serial Number 10/072,247 is an endotracheal tube retainer that is adapted to engage the inside of an endotracheal tube. The OD of the retainer must be in the range of about 2.0 mm to about 14.0 mm to engage an endotracheal tube.

11. The invention claimed in U.S. Patent Application Serial Number 10/072,247 is patentably distinct from the endocardial lead extraction apparatus of the '056 patent because the endocardial lead extraction device does not fall within the size range of devices that are capable of engaging endotracheal tubes.

12. The device of the '056 patent has a diameter that is too narrow to engage an endotracheal tube.

13. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both under §1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the instant application or any patent issued thereon.


Daniel J. Cook


Date

Daniel James Cook, MD

Missouri License #R5G683
Iowa License #24984

1981: BS, University of Iowa, Iowa City, IA
Was graduated with Highest Distinction, 4.00 GPA (A=4)
Major in General Science. Early admission to medical school in
1980

1987: River City Anesthesia, St. Louis & Alton, IL. Staff Anesthesiologist

Accreditations **September 15, 1989 The American Board of Anesthesia**

Patents	US Patent No. 5,937,860, 6,422,239 B1, 6,705,321 B2, 6,443,927, B1 CA Patent No. 2,232,331 UK Patent No. GB 2324040 B, GB 2357437
April 2004	Other US and Foreign patents pending



Products ▾

New Products

Pulse Oximetry

OEM Products

Airway Management

- Endotracheal Tubes
- Tracheostomy Tubes & Accessories
- DAR Filters & Accessories
- Resuscitation Bags
- End-Tidal CO₂ Detectors
- Nebulizers
- Temperature Management
- Sublingual Capnometry
- Critical Care Accessories

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Product Search:

Area of Care

Product Category

Brand Name

Keyword Search

Airway Management | Endotracheal Tubes

Uncuffed Tracheal Tube

Ordering Information

Description	Size	Quantity	Catalog #
Uncuffed Tracheal Tube, Murphy	2.0mm	10/box	86221
	2.5mm	10/box	86222
Uncuffed Tracheal Tube, Murphy	3.0mm	10/box	86223
	3.5mm	10/box	86224
Uncuffed Tracheal Tube, Murphy	4.0mm	10/box	86225
	4.5mm	10/box	86226
Uncuffed Tracheal Tube, Murphy	5.0mm	10/box	86227
	5.5mm	10/box	86228
Uncuffed Tracheal Tube, Murphy	6.0mm	10/box	86229
	6.5mm	10/box	86230
Uncuffed Tracheal Tube, Murphy	7.0mm	10/box	86231
Uncuffed Tracheal Tube, Magill	2.0mm	10/box	86460
	2.5mm	10/box	86461
Uncuffed Tracheal Tube, Magill	3.0mm	10/box	86462
	3.5mm	10/box	86463
Uncuffed Tracheal Tube, Magill	4.0mm	10/box	86464
	4.5mm	10/box	86465

Related Items:

- [Mallinckrodt Tracheal Tubes Quick Guide](#)
- [Product Details](#)
- [View Product](#)

INVENTOR: Daniel J. Cook

DN: COOK 8715 C1

Serial Number: 10/702,247

RETAINER FOR LARYNGEAL MASK

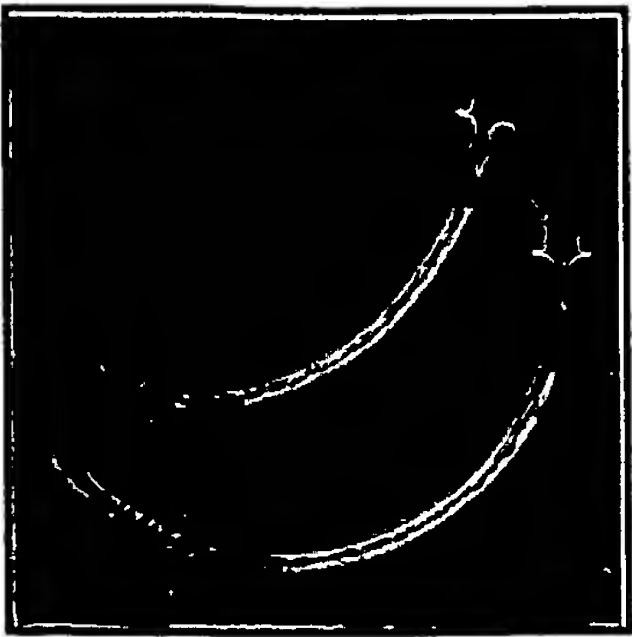
Attorney: Ahaji K. Amos - (314) 238-2400

EXHIBIT 2

SHERIDAN UNCUFFED™ Endotracheal Tubes

Designed for use in th Neonatal and Pediatric OR and ICU.

- Special depth lines at distal tip 1cm apart reference depth of intubation below the vocal cords
- Smooth, molded, gently cupped tip minimizes trauma during intubation
- Tube softens at body temperature to conform to airway anatomy
- Oral/Nasal length available with Murphy Eye or Magill style
- Individually packaged sterile, 10 per case



[View Uncuffed tubes Preloaded with Stylet](#)
[View Uncuffed Tubes with Monitoring Lumen](#)

Cat. No. Uncuffed Murphy	Size I.D.	Cat. No. Uncuffed Magill	Size I.D.
5-10404	2.0mm	5-10504	2.0mm
5-10405	2.5mm	5-10505	2.5mm
5-10406	3.0mm	5-10506	3.0mm
5-10407	3.5mm	5-10507	3.5mm
5-10408	4.0mm	5-10508	4.0mm
5-10409	4.5mm	5-10509	4.5mm
5-10410	5.0mm	5-10510	5.0mm
5-10411	5.5mm	5-10511	5.5mm
5-10412	6.0mm	5-10512	6.0mm
5-10413	6.5mm	5-10513	6.5mm
5-10414	7.0mm	5-10514	7.0mm

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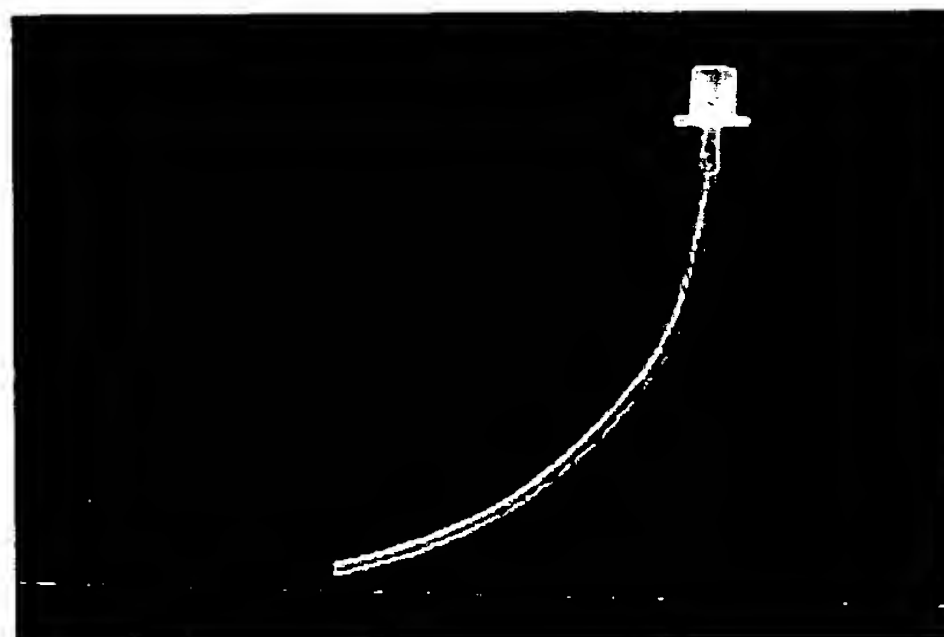
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Ruschelit® PVC. Murphy eye-nasoral. X-ray opaque line.
Graduated. Single use. Sterile



[Product Brochure](#)

	Product Number	Product Description	U/M	Quantity	Latex Content	Sterile
ADD INFO	100382025	Nasoral Uncuf Murphy ET 2.5mm	BX	10	N	Y
ADD INFO	100382030	Nasoral Uncuff Murphy ET 3mm	BX	10	N	Y
ADD INFO	100382035	Nasoral Uncuf Murphy ET 3.5mm	BX	10	N	Y
ADD INFO	100382040	Nasoral Uncuf Murphy ET 4mm	BX	10	N	Y
ADD INFO	100382045	Nasoral Uncuf Murphy ET 4.5mm	BX	10	N	Y
ADD INFO	100382050	Nasoral Uncuf Murphy ET 5mm	BX	10	N	Y
ADD INFO	100382055	Nasoral Uncuf Murphy ET 5.5mm	BX	10	N	Y
ADD INFO	100382060	Nasoral Uncuf Murphy ET 6mm	BX	10	N	Y
ADD INFO	100382065	Nasoral Uncuf Murphy ET 6.5mm	BX	10	N	Y

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Endotracheal

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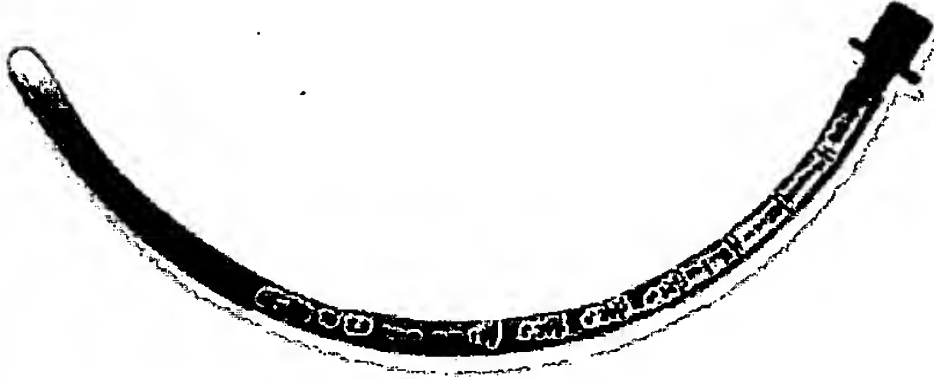
Contact us

Portex

Portex

Intubation General | Uncuffed Endotracheal Tube (Magill shaped)

Portex Siliconised PVC, Oral/Nasal Murphy Eye, Uncuffed Endotracheal Tube



These high quality tubes provide a direct and unimpeded airway for gases to pass to and from the lungs. The tubes are firm enough for ease of intubation yet soften when in place to conform to the anatomy of the upper respiratory tract

Click here for larger image

Product Features and Benefits

Kink-resistant, minimises possibility of tube occlusion

Murphy eye design in the siliconised tube assists bilateral ventilation and a patent airway

Comprehensive size range 2.5–11.0mm to suit all patients

Sizes & Technical Data

■ Siliconised PVC, Oral/Nasal Murphy Eye, Uncuffed Endotracheal Tube.

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Symbols Key

Size ID (mm)	Size OD (mm)	Reference Code
2.5	3.4	100/141/025
3.0	4.2	100/141/030
3.5	4.8	100/141/035
4.0	5.5	100/141/040
4.5	6.2	100/141/045
5.0	6.9	100/141/050
5.5	7.6	100/141/055
6.0	8.2	100/141/060
6.5	8.9	100/141/065
7.0	9.6	100/141/070
7.5	10.3	100/141/075
8.0	10.9	100/141/080*
8.5	11.6	100/141/085*
9.0	12.3	100/141/090*
9.5	13.0	100/141/095*
10	13.7	100/141/100*
10.5	14.4	100/141/105*
11.0	15.0	100/141/110*

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ICD Trials	ICDs	Leads	Programmer	History of ICDs
Electrical Performance	Designed for Reliability	Chronic Performance Tracking	Clinical Results	Specifications

Specifications

Sprint™ 6943	
Polarity	Tripolar
Sensing	True bipolar
Fixation	Extendable/retractable active (helix)
Lead lengths	58, 65, 75, 100 cm
Connectors	DF-1 unipolar high voltage IS-1 bipolar pace/sense
Insulation	Silicone
Tubing design	Multilumen with compression lumens
Tip electrode	CapSureFix® steroid-eluting
Defibrillation electrode shadow area	491 mm ²
Electrode surface areas	6.3 mm ² tip 23.3 mm ² ring 350 mm ² coil
Interelectrode spacing	Tip-ring: 9 mm Ring-coil: 6.3 mm Tip-coil: 18 mm
Electrode lengths	Ring: 2.5 mm Coil: 5 cm
Diameters	7.8 Fr body (2.6 mm) 3.12 mm coil 2.7 mm tip
Introducer	10.5 Fr without guide wire 12 Fr with guide wire
Conductor resistances (65 cm length)	30 Ω to pacing electrode 0.8 Ω to coil
Stylets	Purple (0.016 inches) Gray (0.014 inches)
Serial number prefix	TCE

INVENTOR: Daniel J. Cook
 DN: COOK 8715 C1
 Serial Number: 10/702,247

RETAINER FOR LARYNGEAL MASK
 Attorney: Ahaji K. Amos - (314) 238-2400

EXHIBIT 3


[Indications, Warnings, Precautions, Potential Complications](#)


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ICD Trials	ICDs	Leads	Programmer	History of ICDs
Electrical Performance	Designed for Reliability	Chronic Performance Tracking	Clinical Results	Specifications

Specifications

CapSureFix® 6940

Polarity	Bipolar
Fixation	Screw-in (extendable/retractable helix)
Standard lengths	45, 52, and 58 cm
Connectors	IS-1 B1
Insulation	Silicone with SilaCure®
Tip electrode	CapSureFix steroid-eluting
Electrode surface areas	6.3 mm ² helix 23.3 mm ² ring
Interelectrode spacing	Tip-ring: 9.5 mm
Diameters	7.8 Fr body (2.6 mm) 2.7 mm tip 1.5 mm helix
Introducer	9 Fr (without guidewire) 11 Fr (with guidewire)


[Indications, Warnings, Precautions, Potential Complications](#)
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